Package leaflet: Information for the patient
Etrivex 500 micrograms/g shampoo
Clobetasol propionate

Read all of this leaflet carefully before you start using this medicine because it contains important information for you. Keep this leaflet. You may need to read it again.

If you have any further questions, ask your doctor or your pharmacist.

This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if they have the same symptoms as you.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

1. What Etrivex 500 micrograms/g shampoo is and what it is used for

Etrivex shampoo contains the active substance called clobetasol propionate; it belongs to a group of medicines called topical corticosteroids (or steroids). Topical corticosteroids are further classified into groups depending on their strength. Clobetasol propionate is a very strong corticosteroid. “Topical” means that it should only be applied to the surface of the skin. Topical steroids reduce the redness, itchiness and inflammation associated with skin conditions.

Scalp psoriasis is caused by the skin cells of your scalp being produced too intensely in adults.

2. What you need to know before you use Etrivex 500 micrograms/g shampoo

• If you have been told that you are allergic (hypersensitive) to clobetasol propionate or any of the other ingredients in Etrivex shampoo, please check by reading the list of ingredients listed in section 6 below. If you answer yes, you must inform your doctor before starting treatment.

• If you have bacterial, viral, fungal or parasitic skin infections such as cold sore, varicella (chicken pox), herpes zoster (shingles), impetigo (type of rash on the face), ringworm, athlete foot, thrush, skin tuberculosis or skin disease caused by syphilis.

• If you have ulcerous wounds (weeping wounds) on your scalp.

• If you have used Etrivex shampoo in the eyes or on eyelids (risk of glaucoma which is high pressure in the eye and risk of cataract which is a clouding of the lens in the eye).

3. How to use

Etrivex shampoo is used to treat scalp psoriasis of moderate intensity in adults.

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3. How to use

Etrivex 500 micrograms/g shampoo

- Always use Etrivex Shampoo exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. The usual daily dose per application is an amount equivalent to around a half teaspoon (around 7.5 ml) sufficient to cover the entire scalp.

- Unless your doctor has instructed otherwise, wash your hands and apply Etrivex Shampoo directly to your dry scalp once daily taking care to well cover and massage the affected areas. Avoid using large amounts of Etrivex Shampoo, only use enough to cover your scalp when dry. Wash your hands carefully after application. Leave the product to work for 15 minutes without covering, and then add water, rinse and dry your hair as usual. Your regular shampoo can be used if more shampoo is required to wash your hair. Do not add more of Etrivex shampoo to your hair.

- Your doctor will tell you how long you need to use Etrivex shampoo to control your scalp psoriasis. Treatment should not normally continue for more than 4 weeks. However, if your scalp psoriasis is significantly improved before the end of treatment, please see your doctor. On the contrary, if no improvement is seen by the end of the treatment, please tell your doctor. This treatment needs careful supervision; you should let your doctor review your progress at regular intervals. Do not use Etrivex Shampoo for longer than your doctor tells you.

- Nonetheless, your doctor may ask you to use Etrivex shampoo again in the future following a period of no use.

Use in children and adolescents

If this product has been prescribed for children or adolescents between the ages of 2 and 18 years, the instructions given by your doctor must be followed. You must check with the doctor every week before continuing treatment.

- If you use more Etrivex shampoo than you should

If you have used Etrivex shampoo for much longer than you should, please see your doctor. This product is for use on the scalp only. Do not swallow it. If you accidentally do so, small amounts are not harmful. If you are not sure, seek immediate medical advice.

- If you forget to use Etrivex shampoo

If you forget to use Etrivex shampoo, you must not use a double dose on the next application to make up for a forgotten dose. Go back to your regular schedule. If you miss several doses, tell your doctor.

- If you stop using Etrivex shampoo

If you stop using Etrivex shampoo, please see your doctor. It may be that worsening of the disease occurs when treatment with Etrivex shampoo is stopped, especially if it has been used for a long time. Tell your doctor if you observe such a worsening of your scalp psoriasis conditions.

- If you have any further questions on the use of this product, ask your doctor or pharmacist.
4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Etrivex shampoo may cause the following side effects:

- Skin burning sensation
- Inflammation of one or more hair follicles

Uncommon side effects (may affect up to 1 in 100 people):

- Erythema
- Allergic contact dermatitis
- Skin irritation
- Skin atrophy (thinning of your skin)
- Urticaria
- Dryness of the skin
- Hair loss
- Telangiectasia (veins under the surface of your skin may become more noticeable)
- Psoriasis aggravation
- Hair loss
- Erythema of the skin
- Acne
- Skin oedema
- Telangiectasia (veins under the surface of your skin may become more noticeable)
- Pustular eruptions
- Changes in hair growth and skin colour. Striae (stretch marks) and purpura (bruising) may become noticeable
- If you have no acne (facial erythema associated with flushing of the skin, and possible papulopustules) the application of Etrivex shampoo on the face may cause your skin condition to worsen.
- Application of Etrivex shampoo on the face may induce perioral dermatitis (spotty red rash around the mouth)
- Application of Etrivex Shampoo to the skin may cause thinning of skin and therefore it should never be used on the face or on other areas of the skin than on the scalp.
- In order to avoid interaction with hair dyeing products, such as hair colour changes, Etrivex shampoo should be thoroughly rinsed.
- If you have any unusual discomfort that you do not understand, tell your doctor as soon as possible.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine. United Kingdom: Yellow Card Scheme www.mhra.gov.uk/yellowcard Ireland: HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel +353 1 674971; Fax +353 1 6742517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

5. How to store Etrivex 500 micrograms/g Shampoo

Keep this medicine out of the sight and reach of children. Do not use Etrivex Shampoo after the expiry date which is stated on the bottle and the carton. The expiry date refers to the last day of that month. Store in the original plastic bottle in order to protect from light. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist to throw away medicines you no longer use.

6. Contents of the pack and other information

What Etrivex 500 micrograms/g shampoo contains:
- The active substance is clobetasol propionate
- The other ingredients are: ethanol, coco alkyl dimethyl betaine, sodium laureth sulfate, polyquaternium-10, sodium citrate, cetic acid monohydrate and purified water.

What Etrivex 500 micrograms/g shampoo looks like and contents of the pack

Etrivex Shampoo is a thick, semi-transparent liquid shampoo with an alcoholic smell that is colourless to pale yellow in appearance. Etrivex shampoo is available on prescription from your doctor in white high density polyethylene (HDPE) bottles of 60 ml or 125 ml fitted with polypropylene snap closure. The HDPE bottle of 30 ml is fitted with polypropylene screw closure. Bottles contain 30 ml, 60 ml or 125 ml of shampoo (not all pack sizes may be marketed).

Marketing Authorisation Holder and Manufacturer:

Galderma (UK) Ltd. Mendien House, 68-71 Clarendon Road, Warrington, WA1 2TS, UK. Tel: +44 1925 734950; Fax: +44 1925 734901

Manufacturer:

Laboratoires Galderma, 22, Montsouris 75014, Paris, France.

This medicinal product is authorised in the Member States under the following names:

- United Kingdom, Italy, Ireland and Portugal: Etrivex 500 micrograms/g shampoo
- France, Germany, Belgium, Poland, Spain, Hungary, The Netherlands, Sweden, Denmark, Austria, Luxembourg, Iceland, Czech Republic, Norway, Greece, Slovakia and Finland: Globes 500 microgram/g shampoo

This leaflet was last revised in August 2017.